



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 January 2020  
EMA/139738/2020  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: methadone

Procedure no.: PSUSA/00002004/201905

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
METHADONE AP-HP 1,33 mg/ml, sirop	not available	34009 353 197 9 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
Metadon Abcur 10 mg tablett	SE/H/1288/003	50899	ABCUR AB	SE
Metadon Abcur 40 mg tablett	SE/H/1288/004	50900	ABCUR AB	SE
Metadon Abcur 10 mg tabletit	SE/H/1288/003	32135	ABCUR AB	FI
Metadon Abcur 40 mg tabletit	SE/H/1288/004	32136	ABCUR AB	FI
Metadon Abcur 40 mg töflur	SE/H/1288/004	IS/1/15/026/02	ABCUR AB	IS
Metadon Abcur 10 mg töflur	SE/H/1288/003	IS/1/15/026/01	ABCUR AB	IS
Metadon Abcur 10 mg tablett	SE/H/1288/003	14-10004	ABCUR AB	NO
Metadon Abcur 40 mg tablett	SE/H/1288/004	14-10005	ABCUR AB	NO
Metadon Abcur 10 mg tablett	SE/H/1288/003	32135	ABCUR AB	FI
Metadon Abcur 40 mg tablett	SE/H/1288/004	32136	ABCUR AB	FI
Methadone 1 mg/ml Oral Solution	not available	PL 20416/0481	CRESCENT PHARMA LIMITED	UK
METHADONE AP-HP 1 mg, gélule	not available	34009 379 146 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 5 mg, gélule	not available	34009 379 147 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 10 mg, gélule	not available	34009 379 148 5 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 20	not available	34009 379 149 1 8	ASSISTANCE PUBLIQUE -	FR

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mg, gélule			HOPITAUX DE PARIS - AP-HP	
METHADONE AP-HP 40 mg, gélule	not available	34009 380 508 1 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
Methadon HCl Tiofarma 20 mg, tabletten	not available	RVG 117368	TIOFARMA BV	NL
Methadon HCl Tiofarma 40 mg, tabletten	not available	RVG 117370	TIOFARMA BV	NL
Methadon HCl Tiofarma 80 mg, tabletten	not available	RVG 117371	TIOFARMA BV	NL
Metasedin 30 mg comprimidos.	not available	62.422	ESTEVE PHARMACEUTICALS, S.A.	ES
Metasedin 40 mg comprimidos.	not available	62.423	ESTEVE PHARMACEUTICALS, S.A.	ES
METASEDIN 5 mg Comprimidos	not available	17129	ESTEVE PHARMACEUTICALS, S.A.	ES
Metasedin 10 mg/ml solución inyectable	not available	17.128	ESTEVE PHARMACEUTICALS, S.A.	ES
METHADON HCl DMB 20 mg tabletten	not available	RVG 33036	TIOFARMA BV	NL
MEPHENON 10mg/1ml, oplossing voor injectie	not available	BE117327	LABORATOIRES STEROP	BE
MEPHENON 5mg, tabletten	not available	BE078802	LABORATOIRES STEROP	BE
METHADON HCl DMB 50 mg tabletten	not available	RVG 108360	TIOFARMA BV	NL
Metadon Orion 10 mg tableter	DK/H/2626/002	57800	ORION CORPORATION	DK
Metadon Orion 20 mg tableter	DK/H/2626/003	57801	ORION CORPORATION	DK
Metadon Orion 20 mg tableter	DK/H/2626/003	54802	ORION CORPORATION	SE
Metadon Orion 10 mg	DK/H/2626/002	54801	ORION CORPORATION	SE

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tabletter				
METHADON HCl DMB 10 mg tabletten	not available	RVG 33035	TIOFARMA BV	NL
EPTADONE 20 mg/20 ml sciroppo	not available	006105023	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 10 mg/1ml soluzione iniettabile	not available	006105011	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 10 mg/20 ml sciroppo	not available	006105035	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 1 mg/ml sciroppo	not available	006105062	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 5 mg/20 ml sciroppo	not available	006105047	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
EPTADONE 1 mg/ml sciroppo	not available	006105050	L. MOLteni AND C. DEI F.LLI ALITTI SOCIETÀ DI ESERCIZIO S.P.A.	IT
METHADONE AP-HP 1,33 mg/ml, sirop	not available	34009 353 197 9 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
Methadone 1 mg/ml Oral Solution	not available	PL 20075/0608	ACCORD HEALTHCARE LIMITED	UK
METHADONE AP-HP 1 mg, gélule	not available	34009 379 146 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 5 mg, gélule	not available	34009 379 147 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 10 mg, gélule	not available	34009 379 148 5 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR

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METHADONE AP-HP 20 mg, gélule	not available	34009 379 149 1 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 40 mg, gélule	not available	34009 380 508 1 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, sirop	not available	34009 301 678 4 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, sirop	not available	34009 550 614 3 4	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, sirop	not available	34009 301 679 0 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, sirop	not available	34009 550 614 6 5	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, sirop	not available	34009 301 679 6 0	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, sirop	not available	34009 550 614 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, sirop	not available	34009 301 680 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, sirop	not available	34009 550 615 2 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, sirop	not available	34009 301 678 4 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 5 mg, sirop	not available	34009 550 614 3 4	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-	FR

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			HP	
ZORYON 10 mg, sirop	not available	34009 301 679 0 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 10 mg, sirop	not available	34009 550 614 6 5	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, sirop	not available	34009 301 679 6 0	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 20 mg, sirop	not available	34009 550 614 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, sirop	not available	34009 301 680 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
ZORYON 40 mg, sirop	not available	34009 550 615 2 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
Phymet DTF 1 mg/ml Syrup	not available	PA 1077/074/001	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Methadon-neuraxpharm 10 mg Tabletten	DE/H/4261/002	93817.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
Methadon-neuraxpharm 40 mg Tabletten	DE/H/4261/004	93819.00.00	NEURAXPHARM ARZNEIMITTEL GMBH	DE
METHADONE AP-HP 1 mg, gélule	not available	34009 379 146 2 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 5 mg, gélule	not available	34009 379 147 9 6	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 10 mg, gélule	not available	34009 379 148 5 7	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-	FR

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			HP	
METHADONE AP-HP 20 mg, gélule	not available	34009 379 149 1 8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
METHADONE AP-HP 40 mg, gélule	not available	34009 380 508 1 3	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
Dolmed® 5 mg-tablett	not available	9475	TAKEDA OY	FI
Dolmed 5 mg -tabletti	not available	9475	TAKEDA OY	FI
METHADONE AP-HP 1,33 mg/ml, sirop	not available	34009 353 197 9 1	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS - AP-HP	FR
Methadone Hydrochloride Sugar Free 1mg/1ml Oral Solution	not available	PL 00427/0113	ROSEMONT PHARMACEUTICALS LIMITED	UK